K012081

OCT - 1 2001

DYNAMIC COMPRESSION Shape Memory Alloy (SMA) Staple System 510(k) Summary of Safety and Effectiveness June 2001

I. **Company:** **Medtronic Sofamor Danek, Inc. USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name: DYNAMIC COMPRESSION Shape Memory Alloy (SMA) Staple System**

III. **Product Description**

The DYNAMIC COMPRESSION SMA Staple is fabricated from Nitinol Shape Memory Alloy. This bone fixation device consists of both two and four prong staples and is intended to achieve compression in fixation of bones in the hand, foot, tibia and ankle.

Nitinol can change its configuration (shape) based on temperature. At room temperature, the material is pliant and the staple prongs can be straightened. This allows for easy insertion into the bone. After the staple has reached body temperature, the staple prongs deflect inward to their original shape. This inward deflection causes staple retention and compression across the osteotomy or arthrodesis site. This inward bending creates a claw effect, and helps prevent the staple from backing out of the bone.

IV. **Indications**

The DYNAMIC COMPRESSION SMA Staple System is indicated for use in: (1) Hand and foot bone fragment and osteotomy fixation and joint arthrodesis, (2) Fixation of proximal tibial metaphysis osteotomy, and (3) Fixation of soft tissue to bone such as in anterior cruciate ligament reconstruction.

V. **Substantial Equivalence**

Documentation was provided which demonstrated the DYNAMIC COMPRESSION SMA Staple System to be substantially equivalent to other previously cleared shape memory alloy staples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Dr. Richard W. Treharne
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K012081
Trade Name: Dynamic Compression Shape Memory Alloy (SMA) Staple System
Regulation Number: 888.3030
Regulatory Class: II
Product Code: JDR
Dated: June 29, 2001
Received: July 3, 2001

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012081

Device Name: DYNAMIC COMPRESSION Shape Memory Alloy Staple System

Indications for Use:

The DYNAMIC COMPRESSION SMA Staple System is indicated for use in: (1) Hand and foot bone fragment and osteotomy fixation and joint arthrodesis, (2) Fixation of proximal tibial metaphysis osteotomy, and (3) Fixation of soft tissue to bone such as in anterior cruciate ligament reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use Yes OR Over-the-counter Use No
(Per 21 CFR 801.109)

(Optional 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012081